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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,366	01/28/2004	Pauline Pan	A0000367-03-EJF	2888

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Darryl C. Little, Esq.
Pfizer Inc.
201 Tabor Road
Morris Plains, NJ 07950

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,366	PAN ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-32* is/are pending in the application.

4a) Of the above claim(s) *28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,21-27,31 and 32* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed October 30, 2006. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Objections

Claim 14 is objected to because of the following informalities: there should be a space in between "7" and "wherein" in the first line. Appropriate correction is required.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-19, 21-27, and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 17 recites the limitation "The oral composition of claim" in the first line but does not recite which claims it is referring to. There is insufficient antecedent basis for this limitation in the claim.

2) Claims 1, 3-19, 21-27, and 31-33 recite the phrase "at least one compound of Formula (I)" and then shows one compound. This is indefinite because "at least one compound" indicates there is more than one compound to choose from but one compound is the only choice. This makes the claims indefinite.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 1,6-7, 17, 21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyahara et al. (US 4,693,888).

Miyahara et al. disclose oral compositions comprising compounds such as hinokitiol (claim 26). These compounds are used in combinations with flavorings including essential oils such as peppermint oil, menthol and eugenol. The flavorings comprise 1% of the compositions. The mouthwash compositions comprise 20% ethanol (Example 9). The reference differs from the instant claims insofar as it does not specifically disclose hinokitiol in a composition with an essential oil.

The reference is not anticipatory insofar as one must "pick and choose" from different lists of an effective agent and a flavoring. That being said, it would have been obvious in a self-evident manner to have selected hinokitiol from one list and menthol from another, motivated by the unambiguous disclosure of each individually, and

consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

2) Claims 1, 3-19, 21-27 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fand et al. (US 3,164,524) in view of Iyer et al. (US 5,939,050).

Fand et al. teaches oral antiseptic compositions comprising menthol, thymol, eucalyptol and methyl salicylate. The compositions with this combination of the essential oils have good antiseptic properties. Menthol is incorporated into the compositions from about 20 to about 60 mg, methyl salicylate from about 5 to about 100 mg, thymol from about 50 to about 100 mg and eucalyptol from about 5 to 150 mg, encompassing claims 22 and 26. Ethanol comprises 15 to 30% by volume of the compositions (col. 2, lines 6-20). The reference differs from the instant claims insofar as it does not disclose using hinokitiol in the compositions.

Iyer et al. discloses antimicrobial compositions comprising hinokitiol. It is known that hinokitiol exhibits antimicrobial properties against certain bacteria (col. 1, lines 51-55). It also has a low minimum inhibitory concentration. One property that characterizes the effectiveness of an antimicrobial agent as an anti-plaque and anti-calculus agent is the minimum inhibitory concentration, or MIC, of the agent. At concentrations below the MIC, an antimicrobial agent is ineffective at killing or inhibiting the growth and reproduction of bacteria. At concentrations above the MIC, an antimicrobial agent is effective at killing or inhibiting the growth and reproduction of bacteria. Typically,

antimicrobial agents are introduced into the oral cavity at an initial concentration. Almost immediately, the initial concentration begins to decrease due to the dynamics of the oral cavity. Eventually, the concentration of the antimicrobial agent within the oral cavity will fall below the MIC. Thus, it has been a goal of those working to develop antiplaque and anticalculus formulations to use antimicrobial agents that have low MICs (col. 2, lines 28-50). Other oils that may be in combination with hinokitiol include citronella oil and lemon oil (col. 5, lines 49-63). When hinokitiol is used in combination with the disclosed oils, the MIC value is decreased (see Abstract). Suitable amounts of hinokitiol range from about 0.001 wt. % to about 5.0 wt. %, preferably about 0.01 wt. % to about 2.5 wt. % for each agent based on the total weight of the composition containing the agents (col. 7, lines 12-15), encompassing claim 3. The compositions are effective at inhibiting or preventing the growth of bacteria such as Actinomyces viscosus, Campylobacter rectus, usobacterium nucleatum, Porphyromonas gingivalis, Streptococcus mutans, and Streptococcus sanguis (col. 8, line 67 – col. 9, line 5). The reference differs from the instant claims insofar as it does not disclose menthol, eucalyptus, thymol and methyl salicylate in combination with hinokitiol.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial,* 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to incorporate hinokitiol

into the compositions of the primary reference motivated by the desire to enhance antibacterial activity of the composition with a compound that has a low MIC value to fight bacteria as it starts to lose concentration, as supported by the secondary reference and supported by case law.

3) Claims 1-19, 21-27 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talwar et al. (US 4,945,087) in view of Iyer et al. (US 5,939,050).

Talwar et al. teaches oral compositions comprising thymol and other essential oils. The compositions may be in the form of mouthwashes, toothpaste, liquefied tooth brushing, troches, powders and chewing gums. The compositions comprise thymol, menthol, methyl salicylate and eucalyptol. Thymol is incorporated into the compositions ranging from 0.02 to 0.1% by weight of the composition. The compositions also comprise effective amounts of other essential oils such as eucalyptol, present in amounts of about 0.07 to about 0.11%; menthol, present in amounts of about 0.03% to about 0.06% by weight; and methyl salicylate, present in amounts of about 0.03 to about 0.08% by weight based on the total composition. Ethanol and water are also included into the compositions. Ethanol comprises 5 to 35% of the composition (col. 2, lines 1-12). The reference differs from the instant claims insofar as it does not disclose using hinokitiol in the oral compositions.

The secondary reference, Iyer et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose menthol, eucalyptus, thymol and methyl salicylate in combination with hinokitiol.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial,* 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to incorporate hinokitiol into the compositions of the primary reference motivated by the desire to enhance antibacterial activity of the composition with a compound that has a low MIC value to fight bacteria as it starts to lose concentration, as supported by the secondary reference and supported by case law.

Claims 1-19, 21-27 and 31-32 are rejected.

Claim 14 is objected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614